This request is made on two grounds. First, *applicant had intended to make additional arguments with respect to the prior art rejections before a Second Office Action, and reasonably relied on indications from the Examiner as to when the action would be issued.* Applicants' attorney prepared the arguments and presented them to the Examiner at the interview of January 25. Applicants undertook this considerable trouble and expense with the intention of expediting and advancing the prosecution of the claimed invention. The Examiner expressed interest in the arguments, and requested an additional statistical calculation and a 37 CFR § 1.132 Declaration. In telephone communications with the applicants' attorney after the interview, the Examiner indicated that submission of an additional supplemental amendment would enable her to wait until late March before issuing a Second Office Action. Applicants filed such an amendment on February 1, 1996. On March 12, the Examiner requested that the prior art arguments be filed by about March 15. Applicants hastened to assemble the documents, and applicants' attorney attempted to contact the Examiner on March 14 and 15 to indicate that a response would be filed immediately. Although applicants understood that no action would issue until after March 15, the Examiner mailed the Second Office Action on March 13. Applicants would gladly have provided the documents before that date if it were not for the understanding that the Examiner was waiting to receive them at a later time.

These events have prejudiced applicants' position. Applicants' arguments are now being contemplated by the Examiner after a final rejection. In the spirit of interest and cooperation that both sides have shown heretofore in this matter, applicants respectfully request that the finality of the rejection be withdrawn. This would reinstate the position that applicants would have enjoyed had applicants had a more accurate appreciation of the Examiner's scheduling requirements.

Second, *the finality of the action is improper*. Certain of the rejections are newly made, and pertain to subject matter that was before the Examiner in the original application. In one example, the Examiner rejected claim 1 under 35 USC § 112 ¶ 2 for reciting an

antibody *"having all the identifying characteristics of"* monoclonal antibody 1A7 (¶ 8(a) of the Office Action). The Examiner now asserts that the wording is vague and indefinite as it is not clear what identifying characteristics are intended. The wording was maintained by applicant pursuant to discussions with the Examiner following the interview of January 25. The Examiner had before her in claim 1 of the application *as originally filed* the language that is now deemed to be vague and indefinite. Accordingly, no amendment by applicant necessitated this new grounds of rejection, and the rejection is improper under MPEP § 706.07(a).

In any event, the Examiner indicated that she would entertain new arguments even if a final rejection were issued because they had been discussed during the interview of January 25, 1996.

Regarding claim amendments:

The amendments outlined above are made to clarify the nature of the claimed invention.

Claim 18 has been amended to indicate that the pharmaceutical composition claimed is to include an "effective amount" of monoclonal antibody 1A7. Support for this is found in the specification, *inter alia,* at page 20, lines 13-21.

Claim 26 has been amended in light of the Examiner's comments to indicate that the antibody used to treat the individual from whom the biological sample is obtained is the antibody of claim 1. Support for this is found, *inter alia*, on page 15, line 15 to page 16, line 5.

The added claims have support in the application as filed, and do not constitute new matter. The amendments are made to advance prosecution of the present application, and are not intended to be a dedication to the public of any subject matter of the claims as originally presented.

Regarding objections and rejections under 35 USC § 112:

Claims 1, 4, 7-9, and 10-26 stand rejected under 35 USC § 112 ¶ 2.

Applicants respectfully point out that no reason is indicated for the rejection of claims 13-17 and 19-25 under this Section. Consequently, the rejection of these claims under this Section is improper, and should be withdrawn.

Claims 1 and 11 stand rejected under 35 USC § 112 ¶ 2 as vague and indefinite for reciting "all the identifying characteristics of". Applicants traverse the rejection. A practitioner of ordinary skill in the art will readily appreciate what identifying characteristics are referred to. The Examiner is respectfully reminded that this language is well established as complying with the requirements of this Section, and is incorporated into the claim language of a number of issued US patents. Appendix A attached hereto provides 25 illustrative examples of US patents that have issued between 1982 and 1996, in which this language is used *in the context of defining an antibody molecule*. The Examiner is especially referred to the underlined wording in the examples. Included amongst the examples are US 5,183,756 and US 5,141,865, for which Examiner Robert Budens is an examiner of record. Also included are US 4,709,015, US 5,223,426, and US 5,229,289, for which Examiner Christine Nucker is an examiner of record.

Claim 10 stands rejected under 35 USC § 112 ¶ 2 as vague and indefinite for including in the claim the progeny of the deposited cell line. Applicants respectfully traverse the rejection, as the arguments made by the Examiner are not relevant under § 112 ¶ 2. A practitioner of ordinary skill in the art will readily appreciate what is meant by the progeny of a cell. The claim is therefore neither vague nor indefinite. It is not applicants' intention to limit the claim to particular progeny, nor is such a limitation suggested within the language of the claim. It is perfectly permissible to claim the progeny of a cell which is itself patentable. Appendix B attached hereto provides 9 illustrative examples of issued US patents which

comprise claims to the progeny of a cell. Amongst the examples are US 4,624,921 and US 5,436,154, which include claims to progeny of *antibody producing cells.*

Claim 18 stands rejected under 35 USC § 112 ¶ 2 as vague and indefinite for failing to include more than one compound in a composition. Applicants traverse the rejection. Applicants respectfully remind the Examiner that the pharmaceutical compositions are recited to "comprise" the antibody of claim 11, which is open-ended to include whatever other component may be desirable in a pharmaceutical composition. A pharmaceutical composition need not specify more than one particular component when the specified component is itself patentable. Appendix C attached hereto provides 5 illustrative examples of issued US patents which include claims to pharmaceutical compositions in which only one component is specifically recited. Possible pharmaceutical compositions of the present invention include liquid, solid, and lyophilized formulations. Applicants do not intend to be limited in any way as to components that may be contained in these or any other formulations, except that the antibody of claim 11 must be present. Applicants have amended claim 18 herein to recite that the antibody of claim 11 should be present in an effective amount. Withdrawal of this rejection is respectfully requested.

Claim 26 stands rejected under 35 USC § 112 ¶ 2 as vague and indefinite for reciting treatment with monoclonal antibody 1A7 without referring to the deposited cell line in reference thereto. The claim is herein amended to recite treatment of an individual with the antibody according to claim 1. The antibody of claim 1, in turn, is referred to as having the identifying characteristics of monoclonal antibody 1A7 produced by the cell line on deposit. This addresses the concern of the Examiner. Applicants submit that this rejection has been overcome, and request that it be withdrawn.

Claim 26 also stands rejected under 35 USC § 112 ¶ 2 for not being clear whether the individual was treated subsequently, during or prior to when the sample was taken. Applicants traverse this rejection. It is not applicants' intention to limit the claim to any particular order of treatment and sample collection. Any order may be appropriate, depending

on the intentions of the individual practicing the invention. For example, in monitoring the immune response to treatment with 1A7 antibody, it is often desirable to compare an assay result obtained for a sample taken during or after treatment with a result from a sample taken prior to treatment. The plain wording of the claim includes all the possibilities posed by the Examiner, as the Examiner herself points out. The claim is therefore neither vague nor indefinite in this respect. Applicant requests that this objection be withdrawn.

Claims 1, 4, 11, 12, and 18 stand rejected under 35 USC § 112 ¶ 2 as being of equal scope with other claims. Claims 11, 12, 18, and 19 stand rejected under 35 USC § 112 ¶ 4 as being essentially duplicative of other claims. Applicants traverse these rejections. The enumerated claims are all of different scope, and so cannot be duplicative. An antibody may fall within claim 1 without falling within claim 11. For example, an antibody within the scope of claim 1 need not be purified. An antibody may fall within claim 11 without falling within claim 12. For example, an antibody within the scope of claim 11 may be an antibody with amino acid sequences identical to those of 1A7, but obtained from a source other than the deposited cell line. Claims 4 and 15 depend directly or indirectly from claim 1; claims 18 and 19 depend directly or indirectly from claim 11. Accordingly, claim 18 is of different scope from claim 4, and claim 19 is of different scope from claim 15. Applicants respectfully request that these rejections be withdrawn.

The specification is objected to, and claims 15 and 19 stand rejected under 35 USC § 112 ¶ 1 for failing to teach the administration of Freund's adjuvant to humans without anaphylactic shock. Applicants respectfully traverse this rejection. Applicants disagree with the Examiner's apparent assertion that administration of Freund's adjuvant to humans invariably results in anaphylactic shock. Administration of Freund's adjuvant to humans creates a *small risk* of an anaphylactic reaction, the effects of which may nonetheless be confined by a physician of ordinary skill. Freund's adjuvant has been administered to humans in the past *when the potential benefits of treatment were considered to outweigh the expected risk.* Evaluation of the risk:benefit ratio for any given treatment is the responsibility of the

attending physician, in consultation with the appropriate ethics committees and regulatory agencies. It is not the responsibility of the Patent Office. If the Examiner persists in this rejection, applicants request that she provide proof in accordance with 37 CFR § 1.107(b) to rebut applicants' submission.

Applicants also point out that claims 15 and 19 are not restricted to use in humans, nor is such limitation suggested or intended. The 1A7 antibody may be given as part of a pharmaceutical composition to non-human animals, including those for which the administration of Freund's adjuvant is routine practice. The 1A7 antibody may be given to non-human animals, for example, with the intention of studying the response to 1A7, of producing preparative amounts of anti-GD2, or for developing a model for human cancer treatment. In addition, GD2 is not an antigen that is restricted to humans, but also occurs in other species. A pharmaceutical composition comprising 1A7 therefore has potential for veterinary use. Applicants therefore request that this rejection be withdrawn.

<u>Regarding rejections under 35 USC §§ 102 and 103</u>:

Claims 1 and 10-12 stand rejected under 35 USC § 102(b) over an abstract by Bhattacharya-Chatterjee et al. Claims 1 and 10-12 stand rejected under 35 USC § 103 over Saleh et al. Claims 1, 4, 7-9, and 10-26 stand rejected under 35 USC § 103 over Mujoo et al. in view of Cheung et al.

Applicants respectfully traverse these rejections. These grounds of rejection were addressed in full in the paper filed by applicants on March 18, 1996. Applicants incorporate the submission of March 18 herein, and reassert the arguments therein in response to the §§ 102 and 103 rejections made in Paper No. 11.

Inter alia, arguments and evidence were provided that:

i) The antibody 1A7 has never been made publicly available;

ii) The Bhattacharya-Chatterjee et al. abstract is not enabling for invention claimed in the subject application; and

iii) The 1A7 antibody with its inherent amino acid sequences is unique over the prior art.

The Examiner is respectfully referred to the submission of March 18, including the attachments thereto. Applicants request that the §§ 102 and 103 rejections be reconsidered and withdrawn.

In light of the arguments made herein and previously, applicants respectfully request allowance of all pending claims currently under examination.

If the Examiner wishes to discuss any matter pertaining to this application, she is invited to telephone applicants' attorney at the telephone number listed below.

Respectfully submitted,
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